



**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2015-0814; FRL-9946-13]**

**Pesticides; Draft Guidance for Pesticide Registrants on the Determination of Minor Use**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability.

**SUMMARY:** The Agency is announcing the availability of and seeking public comment on a draft Pesticide Registration Notice (PR Notice) entitled “Determination of Minor Use under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 2(II).” PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This draft PR Notice would update section 5 of PR Notice 97-2 and provide guidance to the registrant as to how the EPA determines a “minor use.” EPA seeks to identify and encourage the registration of pesticides for minor uses to protect communities from harmful pests. This draft PR Notice revises the method used by EPA for evaluating “sufficient economic incentive” under FIFRA. The draft PR Notice explains how qualitative information may be used to inform the quantitative analysis, interpret the results, and clarifies that the most recent United States Department of Agriculture (USDA) Census of Agriculture is the appropriate source for data on acreage in the United States to establish a minor use under the acreage definition in FIFRA 2(II)(1).

**DATES:** Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

**16P-0118**

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0814, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Derek Berwald, Biological and Economic Analysis Division, MC 7503P, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8115; email address: [berwald.derek@epa.gov](mailto:berwald.derek@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are responsible for the initial or continuing registration of pesticides. Entities that register pesticides with EPA's Office of Pesticide Programs typically fall under the North American Industry Classification System (NAICS) Code 325300 – Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing. This action may also be of interest to persons using pesticides on sites that may be considered

“minor” including persons engaged in crop and livestock production, and persons engaged in pest control in residential, commercial, and municipal areas including control of public health pests, and to the public in general. Since many entities may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

*C. How Can I Get Copies of this Document and Other Related Information?*

A copy of the draft PR Notice is available in the docket under docket identification (ID) number EPA-HQ-OPP-2015-0814.

**II. What Guidance Does this PR Notice Provide?**

FIFRA defines a minor use of a pesticide as either (1) a use on a crop grown on 300,000 acres or less in the United States or (2) a use that lacks sufficient economic incentive to seek or maintain a registration but has private or social value. This draft PR Notice provides guidance to the registrant concerning the method used to determine if a use site is a “minor use” as defined by FIFRA 2(II). In particular, the draft PR Notice describes the method for determining if the use

“does not provide sufficient economic incentive.” To date, EPA’s interpretation of *economic* minor use in section 2(II)(2) has been shaped by guidance provided in PR Notice 97-2. However, the approach outlined in PR Notice 97-2 ignores critical factors that influence the incentives for registration.

This draft PR Notice describes the revised approach to evaluate “sufficient economic incentive” which addresses these factors. It explicitly considers (1) the difference in time between incurring costs of generating data for registration and obtaining revenue from product sales, (2) the multiple years over which revenue is generated, and (3) the costs of producing and distributing the product. The draft PR Notice provides suggestions about the data that can be used to conduct the analysis. Finally, the draft PR Notice explains how qualitative information may be used to inform the quantitative analysis and interpret the results. It also clarifies that the most recent USDA Census of Agriculture is the appropriate source for data on acreage in the United States to establish a minor use under the acreage definition in FIFRA section 2(II)(1).

Registrants will typically seek to demonstrate a site is a minor use in the context of requesting an extension of the exclusive use period for data submitted in support of a registration under FIFRA section 3(c)(1)(F)(ii) or a new exclusive use period for data submitted to support a registration under FIFRA section 3(c)(1)(F)(vi). These clauses are intended to provide incentives to registrants to obtain registrations for uses that might otherwise go unfulfilled because they offer low returns because of low demand.

The information collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. The corresponding Information Collection Request (ICR) document for the Application for New and Amended Pesticide

Registration has been assigned EPA ICR number 0277.16 and is approved OMB control number 2070-0060.

### **III. Do PR Notices Contain Binding Requirements?**

The PR Notice about the determination of a minor use is intended to provide guidance to EPA personnel and decision-makers and to pesticide registrants. While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

**Authority:** 7 U.S.C. 136 *et seq.*

Dated: May 31, 2016.

Jack E. Housenger,

*Director, Office of Pesticide Programs.*

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